(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 359 135**
A1

(12) **EUROPEAN PATENT APPLICATION**

(21) Application number: 89116579.7

(51) Int. Cl.5 A63B 71/10

(22) Date of filing: 07.09.89

(30) Priority: 08.09.88 JP 225421/88

(43) Date of publication of application: 21.03.90 Bulletin 90/12

(84) Designated Contracting States: DE FR GB IT

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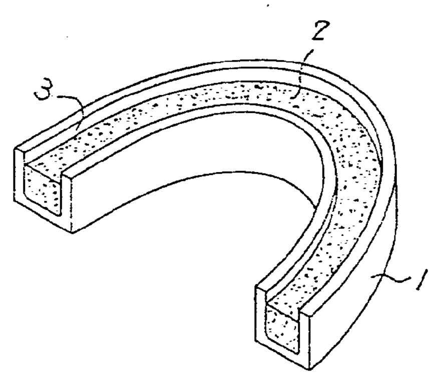
(54) **Mouthpiece.**

(57) A mouthpiece is disclosed which comprises an inner layer material (2, 2a, 2b) put on an inside surface of an outer layer material (1) which is substantially U-shaped so as to cover a row of teeth in a loosely fitted state. The inner layer material comprises an ethylene vinyl-acetate copolymer having a softening point higher than an ordinary temperature in an oral cavity and lower than the highest temperature that an oral cavity can endure. The outer layer material comprises a synthetic resin harmless to a human body and having a softening point higher than the softening point of the inner layer material.

Fig. 1



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MOUTHPIECE

FIELD OF THE INVENTION

The present invention relates to a mouthpiece which is used to protect jaw bone, teeth, and an oral cavity from external force in an contact sport such as rugby football, boxing, or the like, which is used to protect teeth from gnashing in bed.

BACKGROUND OF THE INVENTION

In a contact sport such as rugby football, boxing, or the like, an accident, for example, fracture of jaw bone, a laceration of soft tissue of an oral cavity, or the like, has frequently happened. In order to prevent such an accident from occurring, accordingly, it is conventionally desired to put a mouthpiece in a mouth. The presently existing mouthpieces fitting the above purposes may be classified into three groups as follows.

(1) Mouthpieces of the completed type:

The mouthpieces of this type are mass-produced as standardized goods for a standard row of teeth with a rubbery elastic raw material, and it is therefore impossible to modify the shape of those mouthpieces.

(2) Mouthpieces of the oral-cavity molded type:

Thermoplastic resin or polymerizable resin is used as a raw material for those mouthpieces of this type. The mouthpiece of this type has an U-shaped exterior which may fit a standard row of teeth similarly to the mouthpiece of the completed type, before the mouthpiece is subjected to oral cavity molding. A user soften the mouthpiece by heat or the like and then bites the softened mouthpiece in the oral cavity so that the shape of the user's teeth is transferred to the mouthpiece.

(3) Mouthpieces of the custom-made type:

The mouthpiece of this type is made by a specialist such as a dentist or the like in a manner so that the shape of user's teeth is transferred onto a thermoplastic resin sheet by using a model of the user's teeth through a vacuum molding process or the like.

The mouthpiece of the type (1) has a problem that it is impossible to fit the mouthpiece to the row of teeth having a large individual variation so that the mouthpiece is exceedingly poor in feeling in use, although the mouthpiece of the type (1) can be produced at a low cost.

The mouthpiece of the type (3) has a problem that a burden for a user is large because the producing cost is high and the production of the mouthpiece must depend on a specialist such as a dentist or the like, although the mouthpiece of the type (3) is excellent in fitness to a row of teeth as well as in feeling in use.

The mouthpiece of the type (2), on the other hand, has an advantage in that the mouthpiece can be produced at a low cost and can be produced by a user per se without depending on a dentist. Therefore, it can be said that the mouthpiece of the type (2) is the most desirable one among the foregoing three mouthpieces. Actually realized products of the mouthpiece of the type (2), however, have problems which have not been solved yet.

That is, the actually realized products of the mouthpiece of the type (2) are grouped into two types. (a) One is of the type which is produced in a manner so that the whole mouthpiece is formed of thermoplastic resin, and after heated so as to be softened the synthetic resin is bitten in the user's oral cavity so that the shape of user's teeth is transferred to the synthetic resin to thereby form the mouthpiece. (b) The other is of the type which is constituted by a mouthpiece basic body forming an outer frame and a two-component type polymerizable resin layer applied to an inner surface of the mouthpiece basic body. This type of

mouthpiece is produced in a manner so that the two components of polymerizable resin are mixed with each other immediately before transfer of a shape of user's teeth to thereby generate a polymerizing reaction, the mixed resin is applied to the inner surface of the mouthpiece basic body so as to form the polymerized resin layer, and the thus obtained mouthpiece basic body with the polymerized resin layer is fitted onto the row of user's teeth so that the shape of the teeth is transferred onto the polymerized resin layer in the process where the polymerized resin is hardened as time elapses, as disclosed, for example, in JP-A-62-82984. (The term "JP-A" as used herein means an "unexamined published Japanese patent application".)

The mouthpiece (a), however, is required to have such antithetic performance that flowability is required in production so as to transfer a shape of teeth on one hand and strength sufficient to endure an impact is required in use on the other. There exists however no thermoplastic resin having such inconsistent performances. Therefore, either one of the teeth shape transfer or impression performance and the strength is compelled to be become insufficient. Generally, the fluidability of thermoplastic resin increases to thereby make the impressing performance high as the temperature rises. It is however impossible to raise the heating temperature with the mere purpose of increasing the flowability because the teeth shape transfer is performed in an oral cavity and therefore there is a risk of scald.

In the mouthpiece (b), on the other hand, there is a problem that since two kinds of paste matters (i.e., two-component type polymerizable resin) are mixed with each other, air or a reaction gas may be mixed into the resin mixture in agitating work in the mixing process to generate bubbles to thereby reduce the strength of the mouthpiece after molding. Further, there is a disadvantage that a smell and a bitter taste of the monomer are generated at the time of the polymerizing reaction, so that and a user has a hatred for the teeth shape transfer work. Moreover, the most serious problem is that it is necessary to perform the resin mixing work and to coat the whole inner surface of the mouthpiece basic body with the resin mixture, and therefore the operation is complicated to thereby increase a burden for a user, and that since polymerizable resin cannot be softened again after once hardened, it is impossible to make readjustment even if the shape of teeth changes because of extracting a tooth or the like.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to solve the foregoing problems in the prior art.

It is another object of the present invention to provide a mouthpiece which can be easily produced by a user per se without depending on any specialist such as a dentist or the like, which is improved in impressing performance as well as strength, and which can be easily readjusted if fitness is reduced because of occurrence of a change in the shape of teeth.

The above and other objects and effects of the present invention will be more apparent from the following description.

In order to attain the above objects, according to the present invention, the mouthpiece has a double-layer structure constituted by an outer layer material and an inner layer material. The outer layer material comprises, as a raw material, a synthetic resin harmless to a human body and having a softening point higher than the softening point of the inner layer material, and the outer layer material is substantially U-shaped so as to loosely cover a row of teeth. The inner layer material to be put on the inner surface of the outer layer material comprises, as a raw material, an ethylene vinyl-acetate copolymer (hereinafter, simply referred to as an EVA) having a softening point higher than the ordinary temperature in an oral cavity and lower than the highest temperature that the oral cavity can endure.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view for explaining an embodiment of the mouthpiece according to the present invention; and

Figs. 2 to 4 are views showing other embodiments of the mouthpiece according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The softening point of the inner layer material is preferably 60 °C or less, more preferably 55 °C or less. The softening point of the outer layer material is preferably more than 60 °C, and more preferably from 63 to 68 °C.

Preferred examples of the synthetic resin for the inner layer material which can satisfy not only the above softening point but the required impressing performance, strength, etc. include an EVA having a melt flow rate (hereinafter, referred to as "MFR") of from 30 to 400 g/10min and containing vinyl acetate in an amount of from 19 to 55 wt% based on the total amount of the resin. The MFR of the EVA for the inner layer material is more preferably from 65 to 150 g/10min, and particularly preferably from 65 to 95 g/10min. The vinyl acetate content of the EVA for the inner layer material is more preferably from 28 to 55 wt%, particularly preferably from 28 to 47 wt%, based on the total amount of the resin.

Preferred examples of the synthetic resin satisfying the foregoing conditions for the outer layer material include an EVA having an MFR smaller than 65 g/10min and containing vinyl acetate in an amount of from 6 to 41 wt% based on the total amount of the resin. The MFR of the EVA for the outer layer material is more preferably from 2.5 to 30 g/10min. The vinyl acetate content of the EVA for the outer layer material is preferably from 6 to 33 wt% based on the total amount of the resin.

As described above, the mouthpiece according to the present invention has a double-layer structure constituted by the outer and inner layer materials. The outer layer material has a softening point higher than the softening point of the inner layer material; keeps its substantially U-shaped exterior for covering a row of teeth at a temperature at which the shape of teeth is transferred; and has strength sufficient to endure a strong impact. The inner layer material comprises an EVA having a softening point lower than the highest temperature and higher than the ordinary temperature in an oral cavity.

Therefore, if the mouthpiece is heated to a temperature higher than the softening point of the inner layer material but lower than the softening point of the outer layer material (for example 60 °C, which is higher than the ordinary temperature in an oral cavity but lower than the highest temperature that the oral cavity can endure), the inner layer material has sufficient flowability, so that the shape of teeth can be transferred onto the mouthpiece when the mouthpiece is bitten by a user with a little force. At this time, being not softened at all so as to keep the exterior as it is, the outer layer material acts as an outer frame so that the exterior of the mouthpiece per se is not deformed and no inner layer material flows out even if the inner layer material flows when the mouthpiece is bitten.

At about 37 °C which is an oral cavity temperature in use, the inner layer is hardened with proper elasticity so as to hold the transferred shape of teeth and the mouthpiece is securely fitted onto a row of teeth. On the other hand, the outer layer material becomes stronger at about 37 °C than at, for example, about 60 °C so that the outer layer material can endure stronger external force and the mouthpiece is never damaged even if strong impact force acts on the outer layer material.

Thus, in use, the mouthpiece of the present invention is completely fitted to a shape of the row of teeth through the inner layer material having a shape of teeth transferred thereon and provided with predetermined elasticity to absorb impact force; and, on the other hand, the outer layer material improved in strength endures external force to keep the shape of the mouthpiece to thereby protect the oral cavity.

Since the inner layer material can be easily softened by being heated to a temperature higher than the softening point of the inner layer material but lower than the softening point of the outer layer material, for example, about 60 °C, readjustment of the mouthpiece can be easily made when the shape of teeth row changes because of extracting a tooth or the like.

Further, the inner layer material is fused to the inner surface of the outer layer material in the process of softening the inner layer material, and therefore it is not necessary to use an adhesive for adhesion between the inner and outer layer materials. If the EVA is used for both the inner and outer layer materials, particularly, the adhesion between the materials can be made very firm.

Embodiments of the present invention will be described in detail with reference to the accompanying drawings, but the present invention is not construed as being limited thereto.

Fig. 1 shows one embodiment of the mouthpiece according to the present invention in the state where a shape of teeth is not yet transferred to the mouthpiece.

The mouthpiece has a double-layer structure constituted by an outer layer material 1 and an inner layer material 2 put on the inner surface of the outer layer material 1. The outer layer material 1 is composed of, as its raw material, a synthetic resin having a softening point satisfying a specified condition, and the inner layer material 2 is composed of, as its raw material, an EVA having a softening point satisfying a specified condition.

The outer layer material 1 is molded through an injection molding process, a hollow molding process, a vacuum molding process, or the like, so that the outer layer material 1 is substantially U-shaped so as be fitted to a shape of row of teeth, and a concave groove 3 for fitting a row of teeth therein is longitudinally

formed in the mouthpiece at its central portion in the transversal direction. The size of the outer layer material 1 is selected so that in order to cope with an individual variation in a row of teeth, a slight space to spare is formed between the concave groove 3 and a row of teeth when the row of teeth is fitted into the concave groove 3.

The inner layer material 2 is put into the concave groove 3 formed in the outer layer material 1, for example, by using a method in which the substantially U-shaped outer layer material 1 having the concave groove 3 is formed by molding and the inner layer material 2 molded to be U-shaped is fitted into the concave groove 3 as shown in Fig. 2 or by using a method in which the inner layer material 2 in the fused state is poured into the molded outer layer material 1 so that the outer layer material 1 and the inner layer material 2 are molded integrally with each other.

Figs. 3 and 4 show other embodiments of the method of putting the inner layer material onto the concave groove of the outer layer material. Fig. 3 shows the case where an inner layer material 2a molded to be rod-shaped is transformed to have a substantially U-shaped exterior and then inserted into a concave groove 3. Fig. 4 shows the case where a concave groove 3 is filled with an inner layer material 2b accommodated in a tube 4. In this case, since the inner layer material 2b is in its hardened state at the ordinary temperature, it is necessary to take the inner layer material 2b out of the tube 4 after the inner layer material 2b is softened by soaking the tube 4 into hot water or blowing hot air onto the tube 4.

The inner and outer layer materials having the foregoing exterior shape comprise, as the row materials, synthetic resins having the following characteristics. The inner layer material 2 comprises an EVA or the like having a softening point higher than the ordinary temperature in an oral cavity and lower the highest temperature that the oral cavity can endure, that is, about 70°C and having high flowability in the melted state. Examples of the EVA satisfying the foregoing conditions include an EVA having an MFR of from 30 to 400 g/10min and containing vinyl acetate in an amount of from 19 to 55 wt%. The outer layer material 1 comprises a synthetic resin harmless to a human body and having a softening point higher than the softening point of the inner layer material. Examples of the synthetic resin of this type include an EVA having an MFR smaller than 65 g/10min and containing vinyl acetate in an amount of from 6 to 41 wt%.

As the outer layer material, although it is possible to use any other synthetic resin than the above-mentioned EVA, for example, silicone, polyethylene, ethylene tetrafluoride, styrene butadiene rubber (SBR), acrylonitrile butadiene rubber (NBR), or the like if they are harmless to a human body and have a softening point required for the outer layer material. It is preferable to use the EVA for the outer layer material which is the same kind of synthetic resin as that of the inner layer material, in view of making adhesion between the outer and inner layer materials firm. If the synthetic resin other than the EVA is used as the outer layer material, it is preferable that the outer layer material is formed so as to have a rough inner surface to thereby improve the property of adhesion to the inner layer material.

The reason why the EVA is preferred as the inner and outer layer materials is that attention has been given to the fact that the physical property of the EVA can be remarkably changed in accordance with the MFR and the content of vinyl acetate. The softening point, the strength, the elasticity, and the flexibility of the EVA can be freely adjusted by controlling the MFR and the content of vinyl acetate. That is, the EVA has such a property that the elasticity and the flexibility increase as the content of vinyl acetate increases and that the softening point and the strength decrease as the MFR, which is a physical property value correlated with molecular weight, increases.

Although the EVA has been generally used as the raw material of the conventional mouthpiece, there has been a problem in that the whole mouthpiece is formed of one kind of EVA. Therefore, when the mouthpiece has flowability (that is, the mouthpiece is excellent in impressing performance) at about 60°C which is a temperature at the time of transfer of a shape of teeth, the strength after hardening is so poor that the mouthpiece cannot oppose against external force. When the strength after hardening is increased, on the contrary, there has been a problem that the impressing performance becomes poor.

The mouthpiece according to the present invention has a double-layer structure constituted by the outer layer material and the inner layer material so that only the strength is required for the outer layer material and only the impressing performance and elasticity after hardening are required for the inner layer material. Further, in a preferred embodiment of the present invention, the MFR and the content of vinyl acetate of the outer and inner layer materials are determined under the condition that both the foregoing characteristics and the foregoing softening points are satisfied.

The reason why the MFR and the content of vinyl acetate of the EVA to be used as the inner layer material are selected to be from 30 to 400 g/10min and from 19 to 55 wt% respectively is that the flowability tends to be insufficient at 60° to thereby reduce the impressing performance if the MFR is selected to be 30 g/10min or less and the content of vinyl acetate is selected to be 19 wt% or less. On the other hand, the mouthpiece tends to be not sufficiently hardened at 37°C which is an oral cavity

temperature in use if the MFR is selected to be 400 g/10min or more and the content of vinyl acetate is selected to be 55 wt% or more. When the MFR is set to a value within a range of from 30 to 400 g/10min and the content of vinyl acetate is set to a value within a range of from 19 to 55 wt%, it is possible to obtain an inner layer in which improved impressing performance can be exhibited at 60°C which is a temperature in modeling a row of teeth, and in which a transferred shape of teeth can be maintained and predetermined elasticity is exhibited at 37°C which is an oral cavity temperature in use.

The reason why the MFR and the content of vinyl acetate of the EVA to be used as the outer layer material are selected to be smaller than 65 g/10min and to be from 6 to 41 wt% respectively is that if the MFR is not smaller than 65 g/10min and the content of vinyl acetate is not smaller than 41 wt%, the outer layer material tends to be softened and fused at the temperature at the time of transfer of a shape of teeth so that the exterior shape of the outer layer material cannot be maintained. If the content of vinyl acetate is smaller than 6 wt%, on the other hand, the hardness in use is exceedingly increased to thereby reduce capability of absorbing impact force and feeling in use in an oral cavity is reduced. From the foregoing reasons, when the MFR is set to a value smaller than 65 g/10min and the content of vinyl acetate is set to a value within a range of from 6 to 41 wt%, it is possible to realize the outer layer material which is not deformed even when the outer layer material is heated to the temperature for transferring the shape of teeth and which maintains satisfactory hardness at 37°C which is the temperature in use.

The respective ranges of numerical values of the MFR and the content of vinyl acetate of the above exemplified EVA to be used as the inner layer material are partly coincident with those of the MFR and the content of vinyl acetate of the above exemplified EVA to be used as the outer layer material. However, the same kind of EVA is never used for both the inner and outer layer materials because the outer layer material must have a softening point higher than the softening point of the inner layer material, and the inner layer material must have a softening point higher than an ordinary temperature in the oral cavity and lower than the highest temperature that the oral cavity endure.

Further, additives such as perfumes and colorants may be added to the inner or outer layer materials. Particularly, if a thermally discolorable coloring material is added to the inner layer material, it is possible to visually confirm the temperature state of the inner layer material.

Examples of the manner of use of the mouthpieces of Figs. 1 to 4 are as follows.

A mouthpiece basic body, in which the inner layer materials is put into the outer layer material, is soaked into hot water or hot air is blown onto the mouthpiece basic body by means of a dryer or the like so that the mouthpiece basic body is heated to the transferring temperature, which is higher than the softening point of the inner layer material but lower than the softening point of the outer layer material, for example about 60°C. In the heated basic body, the outer layer is not softened and only the inner layer is softened. The mouthpiece basic body in this state is fitted to a row of teeth and bitten so that a shape of teeth is transferred onto the inner layer.

Although the inner layer has been heated to about 60°C, he temperature is a value that an oral cavity can sufficiently endure, and therefore no scald is generated when the mouthpiece is bitten.

Since the outer layer is not softened so that it is not deformed even if pressing force is exerted on the outer layer when the mouthpiece is bitten. Thus, the inner layer does not flow outside when the mouthpiece is bitten.

When the shape of teeth has been transferred onto the inner layer by biting with user's teeth, the mouthpiece basic body is removed from the row of teeth and cooled to an ordinary temperature in an oral cavity to lower by soaked into cold water so as to harden the inner layer so that the transferred shape of teeth is prevented from being transformed.

The thus completed mouthpiece can protect an oral cavity in a contact sport such as rugby football, boxing, or the like, and can be used as a night guard for preventing gnashing from occurring. For example, in American football, the mouthpiece can be used in the state where the mouthpiece is provide integrally with a stopper attached on a headgear of a helmet.

In the mouthpiece according to the present invention, since the inner layer can be softened only by soaking the mouthpiece into hot water or only blowing hot air from a dryer or the like onto the mouthpiece, it is possible to remold the mouthpiece again and again in the case where a shape of teeth is changed because, for example, of extraction of a tooth to thereby reduce the fitness of the mouthpiece. Further, since the outer layer is not softened by heating, the handling of the mouthpiece is easy and a user can transfer the shape of teeth onto the mouthpiece by the user per se.

If a thermally discolorable coloring material sensitive to a change in temperature is added to the EVA of the inner layer material, it is possible to visually confirm the softened state of the inner layer material when the mouthpiece is soaked into hot water and the hardened state of the same in cooling after transfer of a shape of teeth. Accordingly, the production of the mouthpiece is more easily performed. Further, if perfume

is added to the EVA of the outer or inner layer material, refreshing feeling can be given when the mouthpiece is put in a mouth, so that it is possible to moderate a sense of incompatibility with putting of the mouthpiece.

As described above, the mouthpiece of the present invention is configured so that the inner layer material comprising EVA excellent in impressing performance when softened and excellent in elasticity when hardened is put into the outer layer material comprising a synthetic resin relatively hard and having large strength. According to the present invention, therefore, it is possible to provide a mouthpiece which is easy in transfer of a shape of teeth, which is excellent in impressing performance, which exhibits an improved impact absorption effect in use, and which is excellent in strength. Since the outer and inner layer materials both are formed of the EVA, the materials can be melted so as to firmly adhere to each other, and it is not necessary to use an adhesive. Further, since the mouthpiece of the present invention can be easily remolded, the mouthpiece can cope with the case where a shape of teeth is changed because of extraction of a tooth or the like.

The present invention is described in more detail referring to the following examples but the present invention is not construed as being limited thereto.

EXAMPLE 1

The relationship of the values of the MFR and the content of vinyl acetate to the impressing performance was examined for various EVA resins shown in Table 1.

First, a pair of 10 mm-thick plates were formed from each raw material of the above-mentioned various EVA resins, and the prepared each pair of plates were soaked in hot water of 37° C and 60° C respectively for 15 minutes. Next, the plates were taken out of the hot water, and an upper jaw plaster cast model of a jaw with teeth was put on each of the plates. Then, a load of 1 kg was applied onto the cast model for one minute to thereby press the cast model against the plate so as to transfer the shape of a row of teeth onto the plate. Thereafter, the state of transfer of the row of teeth was observed after removal of the cast model, and the results of transfer were classified into thc following three stages to thereby evaluate the impressing performance of the EVA resins.

2: A shape of teeth can be transferred together with gum portion.
1: A shape of teeth can be transferred only at occlusion surfaces thereof.
0: A shape of teeth cannot be transferred at all.

Table 1 shows the experimental results.

In the Table 1, the respective evaluations of the impressing performance at 60° C and 37° C are written in pair such that the former and the latter are indicated at the left and right of each symbol "/".

Table 1

(Impressing performance at 60° C/37° C)								
	Vinyl acetate content (wt%)							
MFR (g/10min)	55	47	41	33	28	19	12	6
400	2/2	2/2	2/2	2/2	2/0	2/0	1/0	1/0
150	2/2	2/1	2/1	2/0	2/0	1/0	1/0	1/0
95	2/1	2/0	2/0	2/0	2/0	1/0	1/0	1/0
65	2/1	2/0	2/0	2/0	2/0	1/0	1/0	1/0
30	2/0	1/1	1/0	0/0	0/0	0/0	0/0	0/0
15	1/1	1/1	1/0	0/0	0/0	0/0	0/0	0/0
2.5	1/1	1/1	0/0	0/0	0/0	0/0	0/0	0/0

Since it is preferable that the inner layer material is excellent in impressing performance at 60° C and hardened so as not to be deformed at 37° C, it is most preferable that the evaluation is 2/0.

Since it is necessary that the outer layer material is not deformed at both 37° C and 60° C, on the other

hand, it is desirable that the evaluation is 0/0.

When the MFR and the content of vinyl acetate of the inner and outer layer materials were considered counting on a slight tolerance in value from the foregoing point of view, it was found from the results in Table 1 that it was preferable that the MFR and the content of vinyl acetate of the EVA to be used as the inner layer material were selected to be from 30 to 400 g/10min and to be from 19 to 55 wt% respectively, while it was preferable that the MFR and the content of vinyl acetate of the EVA to be used as the outer layer material were selected to be smaller than 65 g/10min and to be from 6 to 41 wt% respectively.

EXAMPLE 2

The impact absorption effect and the strength against external force were measured for various EVA resins and laminates of EVA resins.

A variety of 4mm-thick EVA sheets shown in Table 2, the MFR and the content of vinyl acetate of which were different from each other, were prepared. Glass plates were put on metal plates, and the prepared EVA sheets were put on the respective upper surfaces of the glass plates to cover the glass plate. Next, a 2.5 kg or 3.5 kg loaded shaft rods (diameter: 3.2 mm) were caused to fall vertically from the height of 7 cm, and the state of damage of the glass plates were checked. The experiment was made on five EVA resin sheets for each sample for each rod, and the impact absorption effect was evaluated by counting the number of damaged glass plate(s) of the five glass plates for each sample.

Another experiment was made on the same samples in a manner a follows. A Vicat needle having a mass of 300 g and a sectional area of 1 mm^2 was caused to fall calmly onto each of the samples, and, after 30 seconds, whether the Vicat needle passed through the sample or not was checked to evaluate the strength of the sample. In Table 3, (+) represents the fact that the Vicat needle passed through the sample, and (-) represents the fact that the vicar needle did not pass through the sample.

Table 2 shows the MFR and the content of vinyl acetate in each of the samples of EVA sheets used in the experiment, and Table 3 shows the results of the impact absorption effect test and the strength test.

Table 2

Sample No.	MFR	Content of vinyl acetate	Softening point
	(g/10min)	(wt%)	(°C)
1	12	12	68
2	15	19	65
3	15	28	42
4	65	40	40>
5	95	45	40>
6	(Laminate of Sample Nos. 1 and 4)		
7	(Laminate of Sample Nos. 2 and 4)		
8	(Laminate of Sample Nos. 3 and 4)		
9	(Laminate of Sample Nos. 1 and 5)		
10	(Laminate of Sample Nos. 2 and 5)		
11	(Laminate of Sample Nos. 3 and 5)		

Table 3

	Impact absorption effect		
Sample No.	2.5 kg	3.5 kg	Strength
1	4	5	-
2	0	3	-
3	0	3	-
4	0	1	+
5	0	0	+
6	1	2	-
7	0	0	-
8	0	0	-
9	1	0	-
10	0	0	-
11	0	0	-
No sheet	5	5	-

Among the samples, each of sample Nos. 1 to 5 was a single sheet of EVA. Each of sample Nos. 1, 2, and 3 had the MFR and the content of vinyl acetate preferred for use as the outer layer material. Each of sample Nos. 4 and 5 had the MFR and the content of vinyl acetate preferred for use as the inner layer material. Each of sample Nos. 6 to 11 was a lamination of bonded EVA sheets for outer and inner layer materials respectively.

As seen from Table 3, the sample Nos. 4 and 5 which were the EVA sheets for the inner layer material were poor in strength while they were excellent in impact absorption effect.

On the other hand, the sample Nos. 1 to 3 which were the EVA sheets for the outer layer material were poor in impact absorption effect while they were excellent in strength. It was confirmed that the sample Nos. 6 to 11 each of which was a lamination of bonded EVA sheets for outer and inner layer materials were excellent in impact absorption effect and had sufficient strength.

The mouthpiece according to the present invention is configured so that the inner layer material is put into the outer layer material, the inner layer material comprising, as its raw material, EVA having a softening point higher than the ordinary temperature in an oral cavity and lower than the highest temperature that the oral cavity can endure, the outer layer material comprising, as its raw material, a synthetic resin having a softening point higher than the softening point of the inner layer material and substantially U-shaped so that a row of teeth can be accommodated therein in a loosely fitted state. Therefore, adhesion between the inner and outer layer material can be performed by fusing, and the transfer of a shape of teeth onto the mouthpiece can be performed by softening the inner layer material only by soaking the mouthpiece into hot water or by blowing hot air of a dryer onto the mouthpiece.

Since the inner layer material is high in flowability and excellent in impressing performance, it is possible to obtain a mouthpiece which is excellent in fitness to a row of teeth. Further, since the outer layer material is not softened to thereby maintain the original shape thereof when the inner layer material is softened by hot water or heat of a dryer, no inner layer material flows outside when the mouthpiece is bitten so as to transfer a row of teeth.

Upon using the mouthpiece of the present invention, the outer layer material exhibits excellent strength and the inner layer material exhibits an excellent impact absorption effect because of its elasticity. Therefore, it is possible to provide an ideal mouthpiece for protecting an oral cavity.

Further, according to the present invention, since the inner layer material is formed of thermoplastic resin, it is possible to remold the mouthpiece only heating the mouthpiece again in the case where a shape of teeth is changed because of extraction of a tooth or the like. Accordingly, one mouthpiece can be used for a long period.

In the case where EVA is used also as the outer layer material, it is not necessary to provide an engagement means such as rough-surface treatment or the like on the inner surface of the outer layer material because the adhesive property to the inner layer material is exceedingly excellent.

While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without

departing from the spirit and scope thereof.

Claims

1. A mouthpiece comprising an inner layer material put on an inside surface of an outer layer material which is substantially U-shaped so as to cover a row of teeth in a loosely fitted state,
said inner layer material comprising an ethylene vinyl-acetate copolymer having a softening point higher than an ordinary temperature in an oral cavity and lower than the highest temperature that an oral cavity can endure,
said outer layer material comprising a synthetic resin harmless to a human body and having a softening point higher than the softening point of said inner layer material.

2. A mouthpiece as claimed in claim 1, wherein said inner layer material comprises an ethylene vinyl-acetate copolymer having a melt flow rate of from 30 to 400 g/10min and containing vinyl acetate in an amount of from 19 to 55 wt%; and said outer layer material comprises an ethylene vinyl-acetate copolymer having a melt flow rate smaller than 65 g/10min and containing vinyl acetate in an amount of from 6 to 41 wt%.

3. A mouthpiece as claimed in claim 2, wherein said inner layer material comprises an ethylene vinyl-acetate copolymer having a melt flow rate of from 65 to 150 g/10min and containing vinyl acetate in an amount of from 28 to 55 wt%; and said outer layer material comprises an ethylene vinyl-acetate copolymer having a melt flow rate of from 2.5 to 30 g/10min and containing vinyl acetate in an amount of from 6 to 33 wt%.

4. A mouthpiece as claimed in claim 1, wherein the softening point of said inner layer material is less than 60 °C and the oftening point of said outer layer material is more than 60 °C.

5. A mouthpiece as claimed in claim 4, wherein the softening point of said inner layer material is 55 °C or less and the softening point of said outer layer material is from 63 to 68 °C.

6. A method for producing a mouthpiece comprising the steps of:

(a) heating a mouthpiece basic body comprising an inner layer material put on an inside surface of an outer layer material which is substantially U-shaped so as to cover a row of teeth in a loosely fitted state,
said inner layer material comprising an ethylene vinyl-acetate copolymer having a softening point higher than an ordinary temperature in an oral cavity and lower than the highest temperature that an oral cavity can endure,
said outer layer material comprising a synthetic resin harmless to a human body and having a softening point higher than the softening point of said inner layer material
to a temperature higher than the softening point of said inner layer material but lower than the softening point of said outer layer material;

(b) biting said heated mouthpiece basic body with user's teeth so as to transfer the shape of teeth to said heated mouthpiece basic body; and

(c) cooling said mouthpiece basic body to an ordinary temperature in an oral cavity or lower.

7. A method as claimed in claim 6, wherein said mouthpiece basic body is heated to about 60 °C.

Fig. 1

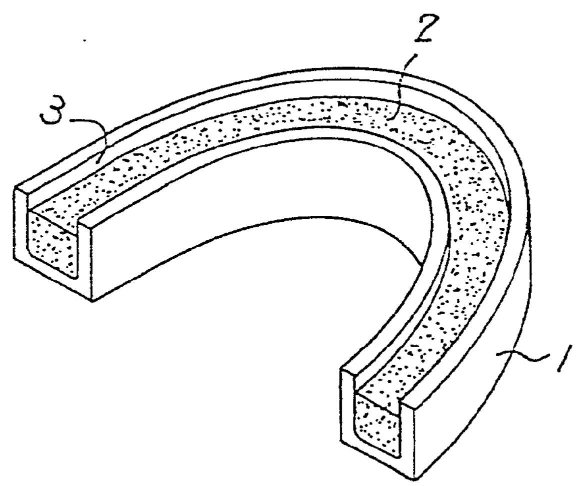


Fig. 2

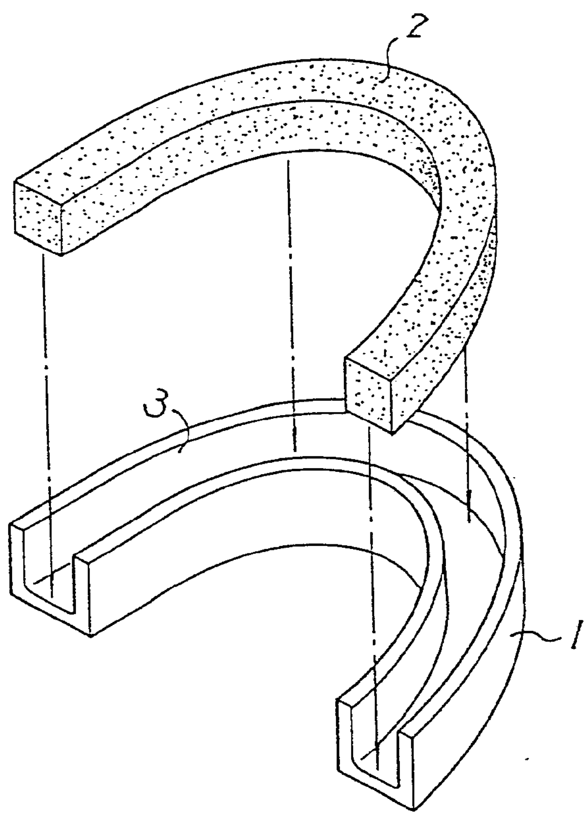


Fig. 3

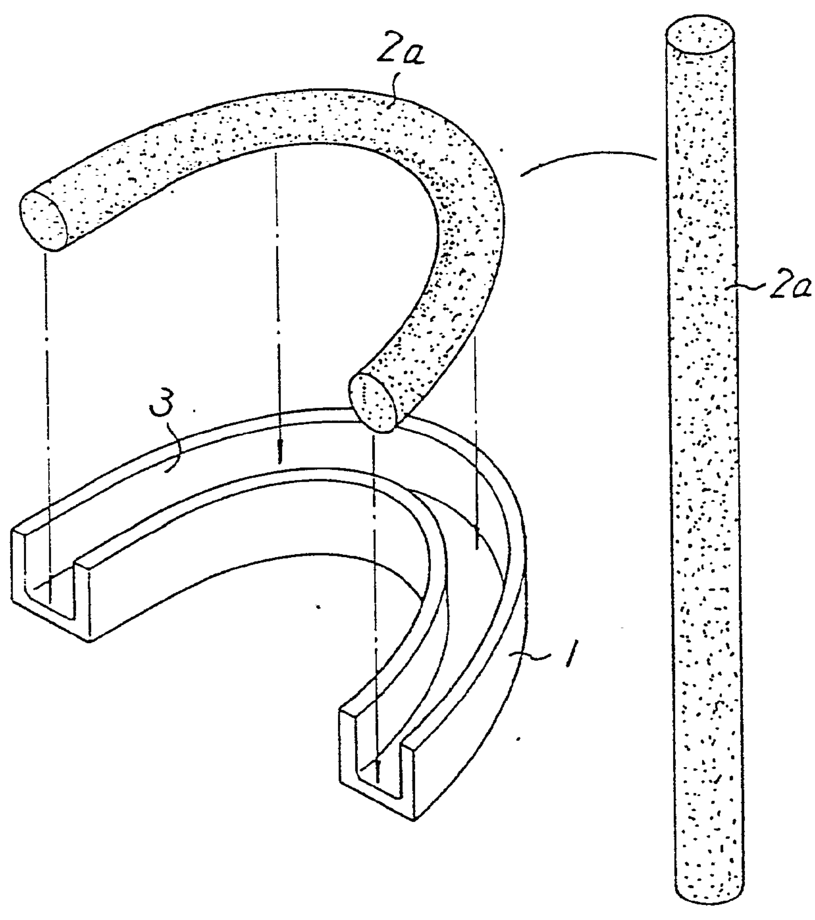
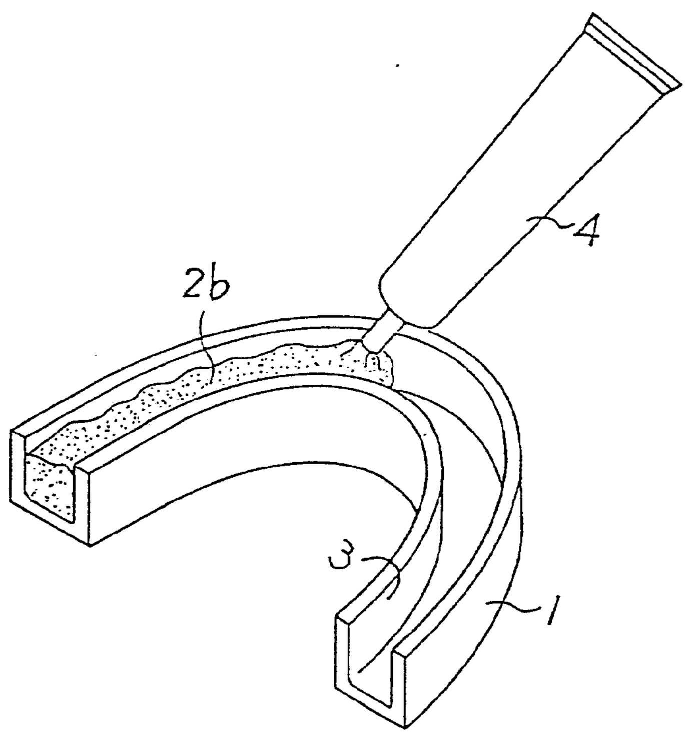


Fig. 4



European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 89116579.7

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US - A - 3 250 272 (GREENBERG) * Totality * --	1,6	A 63 B 71/10
A	US - A - 3 223 085 (GORES) * Totality * --	1,6	
A	US - A - 2 827 899 (ALTIERI) * Totality * --	1,6	
A	US - A - 3 073 300 (BERGHASH) * Totality * --	1,6	
A	US - A - 2 750 941 (CATHCART) * Claims 1-7,11,14,18; fig. * --	1,6	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A	US - A - 3 124 129 (GROSSBERG) * Totality * --	1,6	A 63 B 71/00
D,A	JP - A - 62-82 984 * Totality * ----	1,6	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	04-12-1989	SCHÖNWÄLDER

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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